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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,106	06/04/1999	GULILAT GEBEYEHU	45-93A	3765

23713 7590 09/09/2004

GREENLEE WINNER AND SULLIVAN P C  
5370 MANHATTAN CIRCLE  
SUITE 201  
BOULDER, CO 80303

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/326,106

Applicant(s)

GEBEYEHU ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 105-161 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 124-150 is/are allowed.
- 6) ☒ Claim(s) 105-123 and 151-161 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicants' arguments, filed 6/9/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claims 105-123 and 151-161 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 105 has been amended to indicate that Z – Z bonding is present in the claimed compound and point to Formula I on page 6 of the specification for support. Consideration of said Formula I reveals that bonding between Z groups such as Z – Z bonding is not therein disclosed. Rather the Formula I compounds must contain “n” Formula I moieties but are not limited to any bonding between them. Thus no peptide Z – Z bonding is set forth. Therefore, the amendment to claim 105 regarding such Z – Z bonding is NEW MATTER. This rejection is necessitated by amendment. Claims dependent directly or indirectly from claim 105 are also rejected hereinunder due to their dependence thus causing them to also contain the above NEW MATTER. Claim 108 has been similarly amended regarding Z – Z glycosidic bonds which has not been found

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as filed regarding written support nor pointed to by applicants. This rejection is also necessitated by amendment. Claims dependent directly or indirectly from claim 108 are also rejected hereinunder due to their dependence thus causing them to also contain the above NEW MATTER.

Claim 108 has been amended to add NEW MATTER requiring the  $m = 1$  and  $m = 0$  each at least once in the claimed compound. Applicants point to the specification on page 21, lines 17-31, for support. Consideration of said page 21 citation reveals that a compound with these parameters at least once therein has not been found. It is noted that a polysaccharide comprising 2 – 2000 monosaccharides is disclosed with at least one cationic substituent. This does not correspond to the claim 108 amendment where the  $m = 1$  case would require at least one R group, none of which is a cationic substituent. Also, in said citation a preferred polysaccharide is disclosed with  $m = 0$  but also requiring Z being a modified glucose which is not a limitation of claim 108 either. This rejection is necessitated by amendment. Claims dependent directly or indirectly from claim 108 are also rejected hereinunder due to their dependence thus causing them to also contain the above NEW MATTER.

Claim 161 has been amended regarding R groups “having from about 12 to about 22 carbon atoms”. This amendment is regarding compounds which are of the polyamino acid type as in the first line of claim 161. Applicants have pointed to the specification on page 18, lines 3-6, wherein preferred R groups are 1-alkenyl having about 12 to about 22 carbon atoms. In contrast, however, to instant claim 161 these R groups are particularly 1-alkenyl whereas instant claim 161 lacks the “1-” requirement

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for the alkenyl groups. Thus, the page 18 citation does not correspond to the R groups in claim 161 which thus have been amended with carbon atom limitations which are directed to a specific alkenyl which is not claimed in said claim 161. Additionally, the page 18 citation is directed to Formula VI which is described on page 17 as cationic ceramides and sphingolipids. These compounds are not polyamino acids as in claim 161. This therefore is another difference between the page 18 citation in that it is directed to R groups of ceramides or sphingolipids and not polyamino acids as in claim 161 thus also supporting these R group amendments in claim 161 as being NEW MATTER. Applicants also point to SCHEME 12 on page 51 of the specification. Consideration of said SCHEME 12 reveals also that the compounds with R groups are not polyamino acids as in claim 161. Also the R group disclosure in said SCHEME 12 are directed to 12 to about 24 carbon atoms which is not the same range as in claim 161 and also is directed to thioether groups which are not alkenyl groups as in claim 161. This rejection is necessitated by amendment. Claims dependent directly or indirectly from claim 161 are also rejected hereinunder due to their dependence thus causing them to also contain the above NEW MATTER.

#### **PRODUCT OF NATURE SUBJECT MATTER**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 105, 106, 108, 109, 113, 114, 122, 151, 152, 154, and 161 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, which includes products of nature.

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This rejection is reiterated and maintained from the previous office action, mailed 3/9/04. Applicants argue that the amendment to claim 105 limits the claims to contiguous basic amino acids. In response there is no contiguous limitation seen in claim 105 but rather only that peptide bonds connects Z groups. The fibrillan of Christensen et al. is a polypeptide thus resulting in peptide bonds connecting the amino acids therein as also required in instant claim 105. Claim 161 has been noted above as containing NEW MATTER. This claim remains rejected hereinunder in anticipation of removal of the NEW MATTER leaving the disclosed subject matter therein still rejected as before. Similarly, claims 108 and related claims remain rejected in anticipation of removal of the above described NEW MATTER thus leaving them rejected as before. The mucopeptide based rejection of certain instant claims based on Lehninger at page 233 has been persuasively argued and is hereby withdrawn.

### **PRIOR ART**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 105, 106, 113, 114, 122, and 161 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Christensen et al. [BBRC 155(3):1278 (1988)].

This rejection is maintained and reiterated from the previous office action for reasons of record. Applicants also have argued this rejection with the above 101 non-statutory rejection. These arguments have been responded to above as non-

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persuasive and are equivalently non-persuasive regarding this rejection and reiterated as responses herein.

Claim 161 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lehninger [BIOCHEMISTRY (1970)].

This rejection is maintained and reiterated from the previous office action for reasons of record. Applicants also have argued this rejection with the above 101 non-statutory rejection. These arguments have been responded to above as non-persuasive and are equivalently non-persuasive regarding this rejection and reiterated as responses herein.

Claims 108, 109, 151, 152, and 154 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lehninger [BIOCHEMISTRY (1970)].

This rejection is maintained and reiterated from the previous office action for reasons of record. Applicants also have argued this rejection with the above 101 non-statutory rejection. These arguments have been responded to above as non-persuasive and are equivalently non-persuasive regarding this rejection and reiterated as responses herein.

Claims 124-150 are allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 6, 2004

*Ardin H. Marschel* 9/6/04  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER